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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,392	07/09/2002	John Hefti	JH-003	5837

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EXAMINER	
SINES, BRIAN J	
ART UNIT	PAPER NUMBER
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/064,392	HEFTI, JOHN	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/11/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 4, 8, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 – 4, 8, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

Regarding claims 1 and 8, it is unclear as to how the differential measurements *characterize* the diffusion response occurring between the biochemical species and the reactive constituent along the transport axis and between the first and second measurement probes. It is unclear as to how the measurement probes are used to obtain the necessary measurements. Are concentration values of the biochemical species and the reactive constituent measured with the first and second measurement probes at their respective locations along the transport axis and compared to a baseline diffusion response or calibration data to determine the activity of the biochemical species?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 4, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager (U.S. Pat. No. 6,007,775 A).

Regarding claims 1 and 8, Yager anticipates a diffusion based method and device for detecting the activity of a biochemical species in the presence of a reactive constituent within a diffusion channel (20) (see, e.g., col. 1, line 65 – col. 3, line 20; col. 8, lines 8 – 64; figure 1A). Yager teaches that to measure a detection gradient for an analyte, multiple electrodes can be positioned in series along a diffusion channel (see, e.g., col. 4, lines 48 – 58). Yager teaches that a reagent (150) enters the flow channel through fluid inlet 50 (see col. 8, lines 24 – 31). Yager teaches that a second reagent channel can be positioned downstream of and in series with the first reagent channel for the sequential addition of reagents (see col. 3, lines 7 – 30). Yager teaches that the channel system of the disclosed device and method can be used to measure concentration of an analyte as a function of distance from the reagent inlet. If the analyte concentration is known, the rate of reaction or activity with the reagent can be obtained from the detection gradient (see col. 11, line 62 – col. 12, line 6). Yager teaches performing kinetic measurements (see, e.g., col. 7, lines 21 – 29). It is inherently anticipated that the disclosed method would employ a correlation step for correlating the measured diffusion gradient response to a predefined baseline diffusion response to determine the reaction rate constant or activity of the biochemical species in the presence of the reactive constituent.

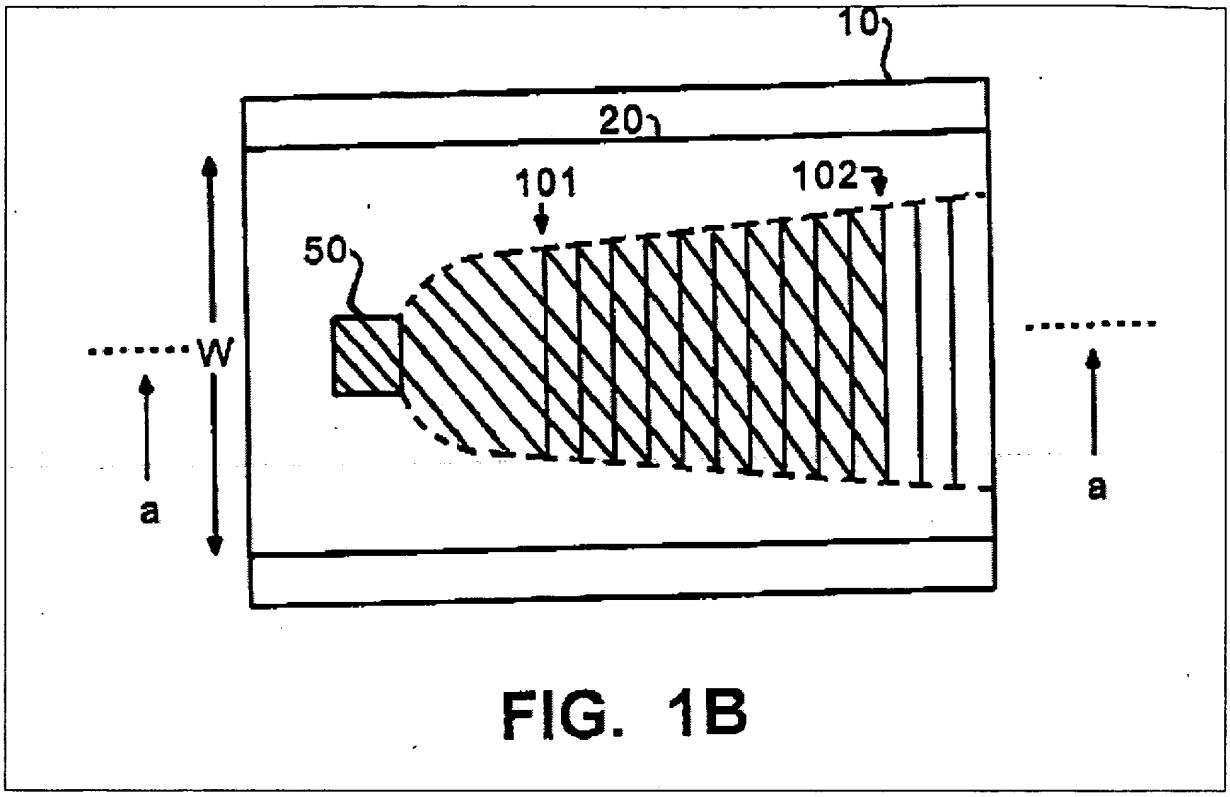

FIG. 1B

Yager anticipates that the analyte particles diffuse into contact and react with reagent particles. The diffusion detection gradient can be observed at the start 101 and at the end 102 of the detection gradient. The presence of analyte is detected by a change in a property, such as absorbance. The concentration of the analyte can be determined from the distance it takes to change the property, and in particular from the detection gradient (see, e.g., col. 8, lines 32 – 47; figure 1B). Furthermore, Yager teaches that to measure the diffusion detection gradient for an analyte, multiple electrodes or probes can be positioned in series along the channel surface and along the transport axis of the channel (see, e.g., col. 4, lines 48 – 58). Therefore, Yager anticipates obtaining a differential measurement between first and second measurement electrodes or probes, wherein the differential measurement characterizes a diffusion response

occurring between the biochemical species and the reactive constituent along the transport axis and between the first and second measurement probes.

Regarding claim 2, Yager teaches that the sample concentration of the biochemical species to be detected can be varied (see col. 3, line 62 – col. 4, line 3).

Regarding claims 3, 4, 11 and 12, Yager teaches that the method can use ionic species and cells, and including therapeutic drugs (see col. 4, lines 5 – 22; col. 10, lines 38 – 63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 4, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager.

Regarding claims 1 and 8, Yager teaches a diffusion based method and device for detecting the activity of a biochemical species in the presence of a reactive constituent within a diffusion channel (20) (see, e.g., col. 1, line 65 – col. 3, line 20; col. 8, lines 8 – 64; figure 1A).

Yager teaches that to measure a detection gradient for an analyte, multiple electrodes can be positioned in series along a diffusion channel (see, e.g., col. 4, lines 48 – 58). Yager teaches that a reagent (150) enters the flow channel through fluid inlet 50 (see col. 8, lines 24 – 31). Yager teaches that a second reagent channel can be positioned downstream of and in series with the first reagent channel for the sequential addition of reagents (see col. 3, lines 7 – 30). Yager teaches that the channel system of the disclosed device and method can be used to measure concentration of an analyte as a function of distance from the reagent inlet. If the analyte concentration is known, the rate of reaction or activity with the reagent can be obtained from the detection gradient (see col. 11, line 62 – col. 12, line 6). Yager teaches performing kinetic measurements (see, e.g., col. 7, lines 21 – 29).

Yager does not specifically teach the use of predefined baseline response data during operation as claimed. However, the use of predefined baseline response data, which would comprise calibration or standard response curves, with detection devices is notoriously well known in the art (see MPEP § 2144.03). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of predefined baseline diffusion response data with the disclosed method to facilitate effective detection and analysis.

As indicated in figure 1B, Yager teaches that the analyte particles diffuse into contact and react with reagent particles (see col. 8, lines 8 – 61). The diffusion detection gradient can be observed at the start 101 and at the end 102 of the detection gradient. The presence of analyte is detected by a change in a property, such as absorbance. The concentration of the analyte can then be determined from the distance it takes to change the property, and in particular from the detection gradient (see, e.g., col. 8, lines 32 – 47; figure 1B). The concentration data can then be

used to determine the activity or rate of reaction of the biochemical species in the presence of the reactive constituent (see, e.g., col. 11, line 62 – col. 12, line 6). Furthermore, Yager teaches that to measure the diffusion detection gradient for an analyte, multiple electrodes or probes can be positioned in series along the channel surface and along the transport axis of the channel (see, e.g., col. 4, lines 48 – 58). It would have been obvious to a person of ordinary skill in the art to position measurement probes at the start 101 and end 102 locations of the diffusion detection gradient to facilitate concentration measurements for the diffusion detection gradient. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the step of obtaining a differential measurement between first and second measurement electrodes or probes, wherein the differential measurement characterizes a diffusion response occurring between the biochemical species and the reactive constituent along the transport axis and between the first and second measurement probes.

Regarding claim 2, Yager teaches that the sample concentration of the biochemical species to be detected can be varied (see col. 3, line 62 – col. 4, line 3).

Regarding claims 3, 4, 11 and 12, Yager teaches that the method can use ionic species and cells, and including therapeutic drugs (see col. 4, lines 5 – 22; col. 10, lines 38 – 63).

Response to Arguments

Regarding the rejection of the present claims under 35 U.S.C. 102(b) as being anticipated by Yager (U.S. Pat. No. 6,007,775 A), Applicant's arguments filed 12/11/2006 have been fully considered but they are not persuasive. The Applicant alleges that Yager does not teach the method of obtaining a differential measurement between a plurality of probes, wherein the differential measurement is used to characterize a diffusion response occurring between the

measurement probes, and subsequently correlating the differential measurement characterizing the diffusion response to second differential measurement characterizing a baseline response as recited in independent claims 1 and 8. However, as indicated figure 1B for example, during the operation of the diffusion-based sensing device of Yager, the analyte particles diffuse into contact and react with reagent particles. The diffusion detection gradient can be observed at the start 101 and at the end 102 of the diffusion detection gradient. The presence of analyte is detected by a change in a property, such as electrochemical or absorbance where the diffusion response can be a change in color. The concentration of the analyte can be determined from the distance it takes to change the property, and in particular from the detection gradient (see, e.g., col. 8, lines 32 – 61; figure 1B). The channel system of the disclosed sensor device can be used to measure the concentration of an analyte during operation. The concentration data can then be used to determine the activity or rate of reaction of the biochemical species in the presence of the reactive constituent (see, e.g., col. 11, line 62 – col. 12, line 6). Yager teaches that to measure the diffusion detection gradient for an analyte, multiple electrodes or probes can be positioned in series along the channel surface and along the transport axis of the channel (see, e.g., col. 4, lines 48 – 58). Therefore, Yager anticipates obtaining a differential measurement between first and second measurement electrodes or probes, wherein the differential measurement characterizes a diffusion response occurring between the biochemical species and the reactive constituent along the transport axis and between the first and second measurement probes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Examiner
Art Unit 1743